

## REMARKS

The Examiner has maintained the rejection under 102(a), that was raised in the previous Office Action rejecting claims 1 to 7 and 9 to 11 as being anticipated by Hu et al. (Nucleic Acid Research, Vol. 26, pg. 5013 to 5015, November 1, 1998) on the ground that the certified copy of the priority document is not present in the case. Applicant provides herewith a Certified Copy of the priority Canadian Patent Application No. 2,245,039, which was filed on August 13, 1998. Removal of the objection is therefore respectfully requested.

Claims 1 to 10 and 13 to 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Fahy. Claims 1 and 12 are objected under 35 U.S.C. 103(a) as being unpatentable over Fahy in view of Resnick et al., and over Fahy in view of Okamoto. These objections are respectfully traversed in view of the amendments to claims 1 and 13. The amendment stipulates that the incomplete set of dNTPs is chosen such that one or more mispair is created in the extension product that terminates the extension. It is respectfully submitted that this amendment makes the claims patentably distinguishable over Fahy and overcomes all the rejections raised by the Examiner.

Claims 16 and 17 have been added to claim additional subject matter to which applicant is entitled.

At this point of the prosecution, applicant respectfully requests an interview with the Examiner to have the opportunity to clearly explain the invention and how the limitation added to claims 1 and 13 clearly distinguishes the present invention from the invention disclosed in Fahy et al.

Separate sheets showing amendment made to the claims set forth above are attached hereto in the attachment entitled "MARKED UP VERSION OF CLAIMS SHOWING CHANGES MADE."

Applicant concomitantly submits a request for continued examination (RCE) with appropriate fee.

Reconsideration of this application is requested.

### **CONCLUSION**

In view of the foregoing amendments and remarks, the applicant respectfully submits that the claims define patentable subject matter. If any questions remain after consideration of the instant amendments, the Office is kindly requested to contact applicant's attorney at the address or telephone number given herein.

Respectfully submitted

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Document in ProLaw

Enclosures:

**Priority Document** 

Request for Continued Examination

Substitute Declaration



# MARKED UP VERSION OF CLAIMS SHOWING CHANGES MADE

### Claim 1 (Twice Amended):

A primer-specific and mispair extension assay for determining genotype, said assay comprising:

- a) extending a nucleic acid sequence from a patient sample with *pfu* DNA polymerase, using a primer specific for a genotype to be determined, and an incomplete set of dNTPs in the absence of ddNTPs, under suitable conditions for obtaining extension products of the primer, such that one or more mispair at a given position relative to 3' end of the primer is created in the extension products that terminates the extension, and wherein at least one of the primer or the dNTPs is labeled;
- b) characterizing the extension products; and
- analyzing the characterized extension products based on primer specific pairing and [mispairing] non-specific pairing to determine the genotype of the nucleic acid sequence extended.

#### Claim 13 (Amended):

A primer-specific and mispair extension assay for determining genotype, said assay comprising:

a) extending a nucleic acid sequence from a patient sample with *pfu* DNA polymerase, using a primer specific for a genotype to be determined, and an incomplete set of dNTPs in the absence of ddNTPs, under suitable conditions for obtaining specific pair and non-specific [mispair] <u>pair</u> extension products of the primer, <u>such that one or more mispair at a given position relative to 3' end of the primer is created in the extension products that terminates the extension, and wherein at least one of the primer or the dNTPs is labeled;</u>

- b) separating the extension products obtained;
- c) characterizing the extension products; [and]
- d) generating a genotype-specific extension profile of the extension products; and
- [d)] e) analysing the genotype-specific extension profiles to determine a genotype of the nucleic acid sequence.